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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,456

01/21/2005

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EXAMINER

AHMED, HASAN SYED

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,456	<b>Applicant(s)</b> ARIEN ET AL.	
	<b>Examiner</b> HASAN S. AHMED	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 12-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/21/05</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of applicants': (a) IDS, which was filed on 21 January 2005 and (b) amendment, which was filed on 18 March 2008.

\* \* \* \* \*

### ***Election/Restrictions***

Applicants' election with traverse (as to Group II) of Group I in the reply filed on 18 March 2008 is acknowledged. The traversal is on the ground that, "...polymer block B represents a polymer comprising at least two different monomers selected from the monomers recited therein." See remarks (filed on 18 March 2008), page 5. This is not found persuasive because Group II (*e.g.* claim 5) does not require at least two different monomers. As such, the scope of Group I differs from Group II and a search burden would exist if the two were searched together.

The remarks filed on 18 March 2008 do not address the species election requirement of the restriction requirement mailed on 19 February 2008. However, in a telephonic interview conducted on 22 May 2008, Attorney Laura A. Donnelly elected claim 2 without traverse.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3-7 and 12-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 March 2008.

\* \* \* \* \*

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,716,203 ("Casey").

Casey teaches a diblock polymer comprising:

- the polymer block A (first block) comprising a linear pharmaceutically acceptable hydrophilic polymer (polyalkylene oxide) of instant claim 1 (see col. 1, lines 8-9);
- the polymer block B (second block) comprising at least two different monomers selected from the group listed therein (glycolic acid and trimethylene) of instant claims 1 and 2 (see col. 1, lines 10-11);
- the diblock copolymer liquid at a temperature below 50°C of instant claim 1 (see col. 2, lines 23-26);
- the diblock copolymer liquid at a temperature below 37°C of instant claim 15 (see col. 2, lines 23-26).

Casey explains that the disclosed diblock polymers are useful as hydrogels in a pharmaceutical composition (see col. 1, lines 39-41).

Casey does not explicitly teach polymer block A with a molecular weight < 1,000 of instant claim 1 or the diblock molecular weights of instant claims 12-14 however, it

would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable polymer weight through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant weight ranges.

Casey teaches a polymer block A of 5 to 25 percent by weight of the copolymer (see col. 1, lines 45-47). Furthermore, the disclosed viscosity (see col. 2, lines 24-26) suggests a diblock polymer weight similar to that being claimed as viscosity is a function of polymer weight.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to disclose a diblock polymer comprising a linear, hydrophilic polymer block A and a polymer block B comprising at least two different monomers, as taught by Casey. One of ordinary skill in the art at the time the invention was made would have been motivated to make such a composition because it is useful hydrogels for pharmaceutical compositions, as explained by Casey.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./  
Examiner, Art Unit 1618

/Humera N. Sheikh/  
Primary Examiner, Art Unit 1618